

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/522,334	03/09/00	WAGNER	R 4257-0018.30

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EXAMINER

KRUSE, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/522,334

Applicant(s)

WAGNER ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Amendment and Remarks, filed 13 August 2001 as Paper No. 11.
2. Claim 13 has been canceled as requested on page 4 of the Amendment filed 13 August 2001.
3. The objection to the disclosure is withdrawn in view of Applicant's amendment to the Specification.
4. The objection to claims 1, 14, 15 and 19 are withdrawn in view of Applicant's amendment to said claims.
5. The rejection of claim 19 under 35 U.S.C. § 112, first paragraph, for scope of enablement is withdrawn.
6. The rejection of claims 1-12 and 16-19 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn in view of Applicant's amendment to said claims.
7. The rejection of claims 1-4 and 19 under 35 U.S.C. § 102(b), as anticipated is withdrawn in view of Applicant's amendments to the claims.
8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

9. Claim 18 remains rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as

set forth in the last Office action mailed 6 April 2001. Applicant's arguments filed 13 August 2001 have been fully considered but they are not persuasive.

Applicant argues that schematic depictions of the pSKI15 and p3202 vectors are provided, and that the specification states the key elements are described on pages 14 and 15 of the Specification (pages 9 and 19 of the Remarks). In addition, Applicant argues that it is well within the knowledge of one of skill in the art to use routine techniques to modify a vector such as pSKI15 to include substitute components, without undue experimentation. The Examiner responds that without a detailed teaching of the assembly process for each of the claimed plant cell expression vectors, or without access to a deposited sample of the claimed vectors, one of skill in the art would now know if the claimed vectors were reproduced, using the guidance in the specification. Hence, it would have required undue trial and error experimentation by one of skill in the art to reproduce each of the claimed vectors. Without such guidance, one of skill in the art would not have known if the claimed vectors had been properly assembled, in order to practice the claimed invention.

10. Claims 14 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because they are dependent upon a cancelled claim, claim 13 has been cancelled as requested on page 4 of the Amendment filed 13 August 2001. Appropriate correction is required.

Claim Rejections - 35 USC § 103

11. Claims 1-12 and 14-19 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hayashi *et al* (Science 1992, 258:1350-1353) in view of Schell *et al* (The Plant Journal 1999, 17(5):461-466). This rejection is repeated for the reason of record as set forth in the last Office action mailed 6 April 2001. Applicant's arguments filed 13 August 2001 have been fully considered but they are not persuasive. This rejection has been modified in view of Applicant's amendments to the claims and Applicant's evidence filed 13 August 2001.

Applicant argues that the teachings of Hayashi were retracted in the supplied references by the Jeff Schell (The EMBO Journal 1999, 18(10):2908, and Trends in Plant Science 1999, 4(6):209) (page 14 of the Remarks). The Examiner responds that the teachings of Schell (1999) state that the activation gene tagging approach as taught by Hayashi remains valid, and that several other researcher have successfully applied the technique in identifying other genes in other plant species, other than tobacco (page 462, right column). The fact that the gene identified by Hayashi proved not to function as taught does not negate the validity of the method.

Applicant argues that the taught method had not been shown to be practical in "fruit-bearing plants" and that the hypocotyls or shoot tip transformation method, employing *Agrobacterium* vectors into plant cells is a novel and non-obvious feature of the current invention (page 14 of the Remarks). The Examiner responds that "fruit-bearing" plants encompass all dicotyledonous plant species, such as tobacco, which produces a capsule fruit. In addition, the use of hypocotyls and shoot tip tissues, and

Art Unit: 1638

Agrobacterium transformation method in transforming a plant cell were well known in the art at the time of Applicant's invention. One of skill in the art at the time of Applicant's invention would have recognized that plant transformation remains an art, requiring optimization of known transformation methods for each plant species. The use of a specific transformation method or plant tissue has not lead to a teaching of unexpected results in the instant invention. Schell (1999) teaches that the method of Hayashi has been used by others to identify genes encoding a desired trait.

In addition, Hayashi teaches transformed plants having enhanced expression of the identified gene (see the Abstract). The claimed method would identify known genes that produce the desired traits of claims 16 and 17. Hence, the transgenic fruit-bearing plant of claim 19 remains obvious in view of Hayashi. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1638

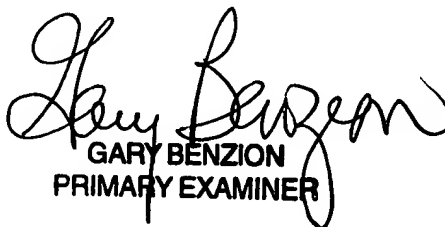
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.


GARY BENZION
PRIMARY EXAMINER

David H. Kruse, Ph.D.
17 October 2001